

REMARKS

Claims 124-130 and 143-149 are pending in the application. None of the claims are amended. Applicants provide a clean set of the claims for the examiner's convenience. The office action is discussed below:

Response to Arguments and Anticipation Rejection:

On pages 2-6 of the Office Action, the examiner states that the arguments, filed on March 23, 2011, are not persuasive and maintains the rejection.

Applicants respectfully disagree with the examiner and traverse the rejection. Applicants submit that the examiner's comments on page 2 regarding Example 6 in Application SN 08/600,744 and on page 3 regarding the photographs of a van de Graaff generator filed on 11-19-2009 appear contradictory. The examiner agreed that the photographs of the van de Graaff generator show a conveyor belt and that multiple doses would be employed to apply 20 Mrads total radiation at 2.5 Mrad/pass when using a conveyor belt method. The examiner asserts that a van de Graaff generator used in Example 6 was relied upon to establish the filing date of 08/600,744. However, the examiner states, what is disclosed in Example 6 in SN 08/600,744, filed 02-13-1996, is that the UHMWPE sample was heated in a chamber (melted) and that an electron beam was irradiated into the chamber through the thin foil at top such that a maximum dose of 20 Mrad was received 5 mm below the surface of the polymer. The examiner also states that Example 6 does not mention a conveyor belt, cycles of radiation or heating the UHMWPE sample to melt after each passage on a conveyor belt through a van de Graaff generator to apply radiation. Applicants submit that Example 6 clearly describes that "Irradiation was done using a van de Graaff generator...." See Example 6 at page 28, lines 13-14, of the original application SN 08/600,744 (filed 02-13-1996). Also see Example 3 at page 24, lines 24-25 that "Irradiation was done using a van de Graaff generator...."

The examiner asserts that the evidence presented does not establish that the use of a van de Graaff generator inherently requires using the conveyor method or

inherently requires heating an UHMWPE sample that was not melted before the first irradiation pass to the melt after each passage through a van de Graaff generator on the conveyor belt. To the examiner, the evidence in the Declaration of Orhun K. Muratoglu filed 03-23-2011 taken with the disclosure in Example 6 of Application 08/600744 is not considered sufficient to show that a method of irradiating UHMWPE and subsequently melting the UHMWPE set forth in the instant claims and disclosed in Application 08/726313, having a filing date of 10-02-1996, was disclosed in application 08/600744, having a filing date of 02-13-1996. The examiner believes that the Declaration establishes that a conveyor belt method can be used with a van de Graaff generator; however, the description of the method employed in Example 6 set forth in 08/600,744 does not mention using a conveyor in the method of irradiation with a van de Graaff generator through thin foil at the top of a chamber containing the UHMWPE sample. Applicants point out that the examiner has misread the Declaration, which provides description and photographs of the van de Graaff generator that was used for the experiment, which also depicts the evidence of use of conveyor belt method.

As discussed above and agreed upon by the examiner that the photographs of the van de Graaff generator show a conveyor belt and that multiple doses are employed to apply 20 Mrads total radiation at 2.5 Mrad/pass, which provides explicit evidence of the disclosure of a conveyor belt method. The declaration further provides description and photographs of the van de Graaff generator, including depicted evidence of use of the conveyer belt for the experiment. Thus, the declaration and the specification provided not only inherent evidence, it also provided sufficient explicit evidence of reduction to practice of the claimed method prior to the filing dates of the cited references.

Therefore, in accordance with the relevant passage in the MPEP with respect to inherent functions or properties in a disclosure, as asserted by the examiner, the specification and the Declaration provide sufficient disclosure to establish inherency, the extrinsic evidence that made it clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency. The examiner also asserts that "mere

fact that a certain thing may result from a given set of circumstances is not sufficient". In the instant case, it was not a mere fact that a van de Graaff generator may be used in a conveyor method, rather the evidence of the van de Graaff generator used in the experiment sufficiently presented to establish that it was used in such a method in Example 6 disclosed in SN 08/600,744.

Applicants mention that the photographs, filed on November 19, 2009, are not photographs of any van der Graaff generator rather are the photographs of the van de Graaff generator that was used to irradiate the UHMWPE sample. Applicants note, the examiner has agreed that a conveyor belt is shown and that irradiation would be performed in multiple doses to reach 20 Mrads if the conveyor belt were employed. However, the examiner has misunderstood that the conveyor belt as shown is not the conveyor belt used in the experiment. Applicants also mention about the passes and cycles of radiations that are evident from the photographs of the van der Graaff generator used.

Thus, the evidence presented in the Rule 1.131 Declaration of Merrill *et al.* filed November 19, 2009 shows reduction to practice of the claimed invention before January 20, 1995. Regarding support from the specification as filed, applicants submit that:

By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971), *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973).

See MPEP §2163.07 (a) (Rev. 6, September 2007 at 2100-192).

Thus, the claimed method was reduced to practice using a van de Graaff generator, which inherently involves heating of the irradiated materials as described in the specification as filed.

Regarding the priority issue, applicants refer to the declaration of Merrill *et al.* that the claimed invention was reduced to practice before January 20, 1995.

Specifically, applicants refer to sections 5 and 10 of the declaration that provide evidences of the conception and reduction to practice of the recited method steps. For example, in the section 5 of the declaration, item b) of Exhibit 1 establishes that prior to January 20, 1995, inventors conceived and reduced to practice a process in which UHMWPE bar stock had been "irradiated and then heated above the melting point". Applicants also quote from the declaration, for example, the inventors state at section 10 of the declaration that "Prior to January 20, 1995, we also developed another embodiment to preserve the highly disordered entangled state of the UHMWPE in order to solve the wear problem (see item b of Exhibit 1). The embodiment involved cross-linking the polyethylene in at room temperature ('cold irradiation') by irradiation and subsequent melting. The process is referred to as Cold-irradiation and Subsequent Melting or "CISM" and is disclosed in U.S. Serial No. 08/726,313"

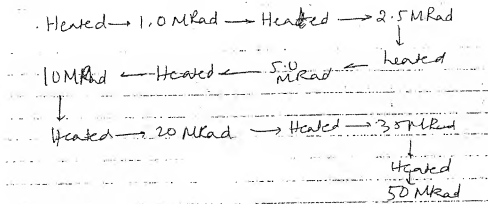
Regarding Shen *et al.* (the '900 patent), the priority issue, as discussed above and as evidenced by the declaration and the Exhibits, applicants submit that the instantly claimed embodiment that recites irradiation is followed by melting, i.e. "IR-SM", was reduced to practice prior to January 20, 1995. Hence, a method that involves irradiation followed by subsequent melting/re-melting was reduced to practice before January 20, 1995. Accordingly, Shen *et al.*, as filed July 9, 1996, is not a prior art to the claimed invention.

Regarding the examiner's comments that "evidence of a concept is not evidence of reduction to practice", applicants submit as agreed by the examiner, that the declaration provides clear evidence of the establishment of the conception, prior to January 20, 1995, at section 5, item b) of Exhibit 1. The invention was reduced to practice, as shown in Exhibit 3, Experiment 1, which involved melting of the irradiated solid UPE. Results of the irradiated and subsequently melted UPE are shown under DSC data Tables filed on May 24, 2004, with the declaration of Merrill *et al.* Regardless of what test method or equipment used to observe the effect of melting of irradiated UPE, the data as recorded in the tables represent the results of the conceived methods as reduced to practice. Thus, the examiner's opinion that DSC may not be considered

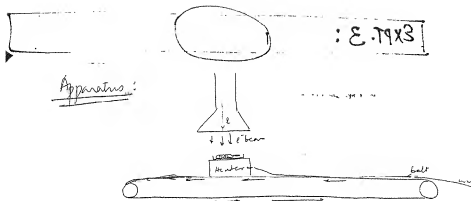
as a heating step (although the process actually involved heating to melt the UPE) is not justified. Accordingly, the declaration provides evidence of the establishment of the conception and reduction to practice of the claimed invention prior to January 20, 1995.

Applicants also request the examiner to consider the response filed in the parent application (Serial No. 10/197,209) regarding irradiation by van de Graaff generator (see pages 5-7 of the response filed May 14, 2008), that when the sample moves outside the e-beam the sample does not receive any radiation dose. However, since the heating continued when the sample is outside of the e-beam, the sample receives heating after each dose of irradiation.

Applicants also request the examiner to considering Dr. Orhun Muratoglu's declaration submitted in a related application, Serial No. 11/184,803. In the declaration, Dr. Muratoglu reviewed the Rule 1.131 declaration, filed on July 16, 2004, and found that Exhibit 3 of the declaration clearly shows that the Experiment 2 describes step by step process of irradiation, heating the consolidated polymer in-between the steps, and continued irradiation and heating until a total dose of up to 50 Mrads is attained (see below, as reproduced from the Exhibit 3):



Applicants point out, Dr. Muratoglu also found that Exhibit 3 of the declaration depicts a sketch of the van de Graaff generator as the radiation source and a consolidated polymer on the conveyer belt passing under the radiation source (see below for the sketch as shown in Experiment 4, source: Exhibit 3 of the declaration):



This depiction shows the irradiation step using van de Graaff generator in the Experiment 4 (also, see the photographs of a common van de Graaff generator in Exhibits 1-4 as filed with the previous response of March 23, 2011).

It is therefore clear to the skilled persons and lay persons alike from the above sketch that there is a pause or the radiation ceases when sample passes out of the radiation zone and the steps of radiation and ceasing radiation are repeated with heating after each dose of radiation until the desired total dose is received by the sample.

In this context, applicants request the examiner to consider the dictates of the MPEP that:

Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph.

See MPEP § 2173.04 (Rev. 6, September 2007 at 2100-220).

By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973).

See MPEP §2163.07 (a) (Rev. 6, September 2007 at 2100-192).

Regarding the priority claim, applicants refer to the Rule 1.131 declaration of Merrill *et al.*, and the clarifications as filed with the previous response that the evidence presented shows reduction to practice of the instantly claimed methods before January 20, 1995. It also was evident that the polyethylene was first melted and then irradiated (see the Declaration of Merrill *et al.*, sections 10-11 and item b of Exhibit 1, for example), which sufficiently provides the evidence of reduction to practice of the claimed method. Hence, a method that involves irradiation is followed by subsequent heating to 150°C or above to treat a UHMWPE was reduced to practice before January 20, 1995. Accordingly, Hyon is not a prior art to the claimed invention.

Applicants also refer the examiner to Dr. Orhun Muratoglu's declaration in a related U.S. Patent Application No. 11/184,803, in which Dr. Muratoglu reviewed Rule 1.131 Merrill declaration, and found that Irradiation and Subsequent Melting embodiment was conceived and reduced to practice prior to January 20, 1995.

In view of the above explanations, applicants submit that Shen *et al.* and Hyon *et al.* are not prior art to the claimed invention.

Claim Interpretation and Effective Filing Date:

On pages 6-7 of the Office Action, the examiner states that claims 124-127, 130 and 143-149, recite a process wherein irradiation of UHMWPE is subsequently followed by heating or melting; a method ("IR-SM") first disclosed in 124-127, 130 and 143-149, wherein the irradiation step precedes the melting step have an effective filing date of October 2, 1996, and February 13, 1996, which is the filing date of the priority application SN 08/600,744.

Therefore, the examiner considers that the earliest effective filing date of the instant claims 124-127, 130 and 143-149, wherein the method steps comprise irradiation followed by melting the irradiated UHMWPE is considered to be the October 2, 1996 filing date of SN 08/726,313.

Applicants disagree with the examiner and submit, as discussed above and as evidenced by the declaration and the Exhibits, that the instantly claimed embodiment,

wherein heating of the irradiated materials at 150°C or above and cooling thereafter, was reduced to practice prior to January 20, 1995.

Regarding the priority claim, applicants request the examiner to consider the Rule 1.131 Declaration of Merrill *et al.*, filed June 8, 2007, in a related case U.S. Application Serial No. 10/696,362 (MERRILL *et al.*, copy provided with the response filed on November 19, 2009). Applicants also refer the examiner to the evidence in the Declaration of Merrill *et al.*, filed June 8, 2007 under Rule 1.131, which the examiner has agreed (see Office Action of September 7, 2007, page 2, in the US application serial no. 10/696,362), that the evidence presented shows reduction to practice of the instantly claimed methods before January 20, 1995 (see the Declaration of Merrill *et al.*, sections 10-11 and item b of Exhibit 1, for example), which sufficiently provides the evidence of reduction to practice of the claimed method that involves heating of the irradiated materials at 150°C or above and cooling thereafter.

On pages 6-7 of the Office Action, the examiner also asserts that claims 128-129 are not supported by the disclosure of SN 08/600,744, which does not disclose the swell ratio or degree of oxidation of the crosslinked UHMWPE, thus, are not entitled to the February 13, 1996 date. Applicants disagree and refer to the original specification, see for example, Example 4, Tables 2 and 6; and Example 11, Tables 8 and 11 for support.

In view of the above clarifications, applicants submit that Shen *et al.* (the '900 patent) and Hyon *et al.* (the '626 patent), are not prior art to the claimed invention.

Double Patenting Rejections, Withdrawn in Part:

On pages 8-10 of the office action, the examiner has maintained the provisional obviousness-type double patenting rejection of the claims and alleged as being directed to the same invention as the claims of co-pending U.S. application serial nos. 10/948,440, 10/197,209, 10/696,362, and 10/197,263.

Applicants reiterate, since a notice of allowability has not been issued for any of the U.S. application serial nos. 10/948,440, 10/197,209, 10/696,362, and 10/197,263,

the merits of this provisional rejection need not be discussed with the examiner at this time. See MPEP § 822.01, more specifically, see MPEP § 804 I.B.

Between Copending Applications-Provisional Rejections

Occasionally, the examiner becomes aware of two copending applications that were filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee, or that claim an invention resulting from activities undertaken within the scope of a joint research agreement as defined in 35 U.S.C. 103(c)(2) and (3), that would raise an issue of double patenting if one of the applications became a patent. Where this issue can be addressed without violating the confidential status of applications (35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting. *In re Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau*, 356 F.2d 556, 148 USPQ 499 (CCPA 1966). The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue.

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.

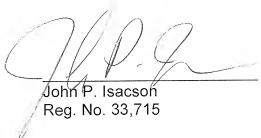
Accordingly, the provisional double-patenting rejection over the co-pending U.S. application serial nos. 10/948,440, 10/197,209, 10/696,362, and 10/197,263 should be withdrawn.

With respect to the recently allowed U.S. application serial no. 10/901,089 (the '089 application, now U.S. Patent No. 7,858,671), the examiner apparently has withdrawn the rejection in view of the arguments presented on March 23, 2011. Applicants thank the examiner for the withdrawal of this rejection.

REQUEST

Applicants submit that claims 124-130 and 143-149 are in condition for allowance, and respectfully request favorable consideration to that effect so that an interference can be declared with applicants as the senior party by virtue of the priority afforded by the priority applications. The examiner is invited to contact the undersigned at (202) 628-6600 should there be any questions.

Respectfully submitted,



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